REMARKS

Claims 1-5 and 8-17 were pending. Claim 1 was amended. Claim 17 was cancelled. Therefore, claims 1-5 and 8-16 will be pending upon entry of this amendment.

No new matter was added. Support for the amendment to claim 1 can be found in claim 15 as originally filed or in the specification, for example, at least at page 5, lines 28-29.

The specification was amended to remove incorporations by reference as requested by the Examiner. No new matter was added.

Rejection of Claims 1-5 and 8-17 under 35 U.S.C. § 102(e)

Claims 1-5 and 8-17 are rejected under 35 U.S.C. § 102(e) as being anticipated by MacPhee *et al.* (U.S. 6,197,325). Claim 17 has been cancelled, thus rendering its rejection moot. According to the Examiner, MacPhee *et al.* "at claim 18 discloses the utility of N,O-dicarboxymethylchitosans (NOCC) based compositions in the introduction of medicinal compounds to moist tissues to permit the sustained release of the medicinal compound into said tissue." Applicants disagree.

Applicants claim a method of providing sustained release of a drug to moist tissue by applying to the moist tissue a drug delivery device. Claim 1 has been amended to add a definition of moist tissue; the moist tissue is mucosal tissue or tissue in a serous cavity. See page 5 of the specification for support for this amendment. The claimed drug delivery device is adherent to the moist tissue and includes N,O-carboxymethylchitosan as a component to provide the adherence. The drug delivery device also contains a sufficient quantity of the drug to be delivered to provide sustained release of the drug and permeation into the moist tissue or into the surrounding cavity.

MacPhee *et al.* describe tissue sealants, such as fibrin glue, which use fibrinogen to promote the generation or regeneration of bone and/or cartilage. It described the use of chitosans only as material suitable for "preparing the biodegradable backing" for the treatment of bone or cartilage. Bone or cartilage are not moist tissues as defined in claim 1. Thus, MacPhee fails not only to teach or suggest the use of NOCC as an adherent for use in a drug delivery device which uses NOCC to provide the adherence, it also fails to teach or suggest the use of NOCC to treat mucosal tissues and tissues in serous cavities.

Therefore, MacPhee *et al.* fails to teach or suggest the claimed method of providing sustained release of a drug to mucosal tissue or tissue in a serous cavity by using a drug delivery device which uses NOCC as a component to provide the adherence.

Therefore, Applicants respectfully request that this rejection of claims 1-5 and 8-16 under 35 U.S.C. § 102 (e) be withdrawn.

Rejection of Claims 1-5 and 8-17 under 35 U.S.C. § 102 (b)

Claims 1-5 and 8-17 are rejected under 35 U.S.C. § 102(e) as being anticipated by Elson (U.S. 5,888,988). According to the Examiner, Elson discloses "covalent linking of NOCC with a variety of different pharmaceutical substances to permit administration of the NOCC derivatives formed thereby as a gel to provide sustained *in vivo* release of the linked substance." Applicants disagree that this reference anticipates or renders obvious the claimed subject matter.

As described above, Applicants claim a method of providing sustained release of a drug to moist tissue by applying and adhering to the moist tissue a drug delivery device, which uses NOCC to provide the adherence.

Elson describes the use of NOCC and cross linked NOCC gels as drug carriers. Elson does not teach or suggest the use of NOCC as an adherent or as an adherent component of a drug delivery device. Not all gels or solutions of NOCC are adhered. Elson fails to teach or suggest a drug delivery device which uses NOCC as a component to provide adherence or a method of using one. Therefore, Applicants respectfully request that this rejection of claims 1-5 and 8-16 under 35 U.S.C. § 102 (b) be withdrawn.

CONCLUSION

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of and/or amendments to the claims are being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application.

In light of the foregoing, Applicants consider that the claims, as amended, are in condition for allowance. Prompt notification of allowance is requested.

Respectfully submitted,
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